Alabama Medicaid DUR Board Meeting Minutes
April 25, 2012

Members Present: Paula Thompson, Kelli Littlejohn, Bernie Olin, Denyse Thornley-Brown, Wendy Gomez, Dan McConaghy, Daniels Mims, Donald Marks, Robert Moon

Also Present: Clemice Hurst, Tiffany Minnifield, Heather Vega, Lori Thomas, Steve Espy

Present via Conference Call: Chris Barwick, Cara Leos, Amanda Sparkman

Members Absent: Rhonda Harden, David Harwood, Yves Morrisette

Call to Order: The DUR meeting was called to order by P.Thompson at approximately 1:00p.m.

Review and Adoption of Minutes: The minutes of the January 25, 2012 meeting were presented and reviewed. D.Thornley-Brown made a motion to approve the minutes as presented and R. Moon seconded the motion. The motion was approved unanimously.

Prior Authorization and Overrides Update: L.Thomas began the Prior Authorization and Overrides Update with the Monthly Manual Prior Authorizations and Overrides Report for the month of November 2011. She reported 9,981 total requests. She then reported 26,068 electronic requests for the same time frame. From the Prior Authorization and Override Response Time Ratio report for November 2011, L.Thomas reported that approximately 84-85% of all manual PAs were responded to in less than two hours, about 96% in less than four hours and 99% in less than eight hours. For the month of December 2011, L.Thomas reported 9,211 manual PA requests and 20,877 electronic PA requests. She reported that more than 91% of PAs were responded to in less than two hours, approximately 98% in less than four hours and 99% in less than eight hours. For the month of January 2012, L.Thomas reported 10,131 manual PA requests and 22,543 electronic PA requests for the same time frame. For January, L.Thomas reported 93% approved in less than two hours, approximately 99% in less than four hours and 99% approved in less than eight hours. L.Thomas reminded the Board that the large increase in manual and electronic PA requests is due to the implementation of the antipsychotic edit in October 2011.

Program Summary Review: L.Thomas briefly reviewed the Alabama Medicaid Program Summary. She reported 4,436,633 total prescriptions, 234,547 average recipients per month and an average paid per prescription of $59.51 for the months of July 2011 through December 2011.

Cost Management Analysis: L.Thomas reported an average cost per claim of $59.73 for December 2011 and $59.15 for January 2010. J. Jackson asked why there was an increase in recipients. K. Littlejohn responded that there is generally a five to seven percent increase in recipients annually. She also noted that in 2014, there will be a larger increase in recipients due to the Affordable Care Act. From the 4th Quarter 2011 Drug Analysis, L.Thomas reported 75.31% generic utilization, 13.48% brand single-source, 3.71% brand multi-source (those requests which required a DAW override) and 7.50% OTC and "other". L. Thomas commented that the stats were very similar to what was reported for the previous quarter. From the Top 25 Drugs Based on Number of Claims from 10/01/2011 – 12/31/2011, L.Thomas reported the top five drugs: hydrocodone-acetaminophen, amoxicillin, Bromfed® DM, azithromycin and Singulair®. L. Thomas informed the Board that the inclusion of Bromfed DM in the top five drugs was related to the FDA's removal of many cough and cold products. She also mentioned that utilization has shifted to products that are covered by Alabama Medicaid and available at most pharmacies. She then reported the top five

drugs from the Top 25 Drugs Based on Claims Cost from 10/01/2011 – 12/31/2011: Singulair, Synagis®, Abilify®, Vyvanse® and Novoseven RT®. L. Thomas mentioned that Zyprexa® became generic in November, thus removing it from the top five drugs as it had been in previous quarters. L. Thomas reminded the members that Synagis season ended in March. From the Top 15 Therapeutic Classes by Total Cost of Claims for the same time frame, L.Thomas reported the top five classes: Antipsychotic Agents, Hemostatics, Corticosteroids (Respiratory Tract), Leukotriene Modifiers, and Amphetamines. She pointed out that the number of antipsychotic claims has decreased by 5000 and that the total cost of antipsychotic claims has decreased by 4% from the previous quarter. The graphs referring to the Top 25 Drugs Based on Total Claims Cost and the Top 25 Drugs Based on Number of Claims were corrected to reflect the correct data. Corrected pages will be provided to members at the next meeting when they approve the minutes.

UPDATES

Hydrocodone Utilization: At the January 2012 DUR Meeting, the Board requested that HID present information pertaining to the utilization of hydrocodone products. L. Thomas reported this information, as shown in the following table:

Date Range	Category	Quantity
01/01/2011 – 12/31/2011	Total hydrocodone claims	335, 308
06/01/2011 – 12/31/2011	Total hydrocodone claims	198,887
06/01/2011 – 12/31/2011	Unique recipients receiving more than the recommended maximum quantity per month	2,435

L. Thomas also presented the number of hydrocodone claims by strength of hydrocodone, as shown in the following table:

Date Range	Category	Quantity
06/01/2011 – 12/31/2011	Hydrocodone claims, 2.5mg	575
	Hydrocodone claims, 5mg	41,826
	Hydrocodone claims, 7.5mg	78,719
	Hydrocodone claims, 10mg	67, 227
	Hydrocodone claims, Solution	10,504

L. Thomas reported the top five prescriber specialty codes of prescribers writing prescriptions for hydrocodone along with the quantity of prescriptions written by each prescriber. She then reported the top five diagnosis codes from the Top 25 Diagnosis Codes for Recipients Receiving Hydrocodone.

The Board also suggested that a report be provided showing the number of recipients taking hydrocodone along with a non-narcotic adjuvant therapy and a report showing hydrocodone utilization in recipients less than 18 years of age.

Prescription Drug Monitoring Program Overview: S. Espy presented an overview of the Alabama Prescription Drug Monitoring Program (PDMP). S. Espy began with a brief history of the PDMP and the purpose of the program. S. Espy described the entities that are required to report data to the PDMP, who has access to the data in the PDMP database, and different methods used to access the data. S. Espy provided several examples of geographical reporting and utilization reporting. S. Espy concluded the presentation by discussing upcoming enhancements to the program.

Proposed Criteria: L.Thomas presented the proposed set of 16 criteria to the Board. P.Thompson requested clarification on criteria #16. T.Minnifield instructed the Board members to mark their ballots. Of the 18 criteria, results from the criteria vote returned 17 approved, 0 rejected and 1 criteria approved as amended (#16).

Medicaid Update: T. Minnifield began the Medicaid Update by pointing out to the members that there will be a vote for Vice Chair at the next meeting. She also reminded the Board members that all Medicaid information discussed is available online. K. Littlejohn discussed the resignation of Dr. Mullins and the appointment of Don Williamson to lead the transition in leadership at the agency. K. Littlejohn briefed the Board members on the budgetary issues that the agency is facing. K. Littlejohn was hopeful that there would be a budget finalized by the next meeting.

P & T Committee Update: C.Hurst began the P&T Update by informing the Board that the last meeting was held on February 8, 2011 and covered the first round of the Anti-Infective agents. The next P&T meeting is scheduled to be held May 9, 2012 at 9am and will cover the remaining Anti-Infective agents. C. Hurst also discussed the PDL changes that were effective April 2, 2012.

New Business: There being no new business, P.Thompson asked for a motion to adjourn. D.Thornley-Brown made a motion to adjourn the meeting. The motion was seconded by B.Olin. A voice vote to adjourn was unanimous. The meeting was adjourned at 2:30 p.m.

Next Meeting Date: The next DUR Board meeting will be held on July 25, 2012.

Respectfully submitted,

Lori Thomas, PharmD

Lori Thomas, PharmD

ALABAMA MEDICAID RETROSPECTIVE DRUG UTILIZATION REVIEW CRITERIA RECOMMENDATIONS

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*
1. Dronedarone / Warfarin Alert Message: Post-marketing cases of increased INR with or without bleeding events have been reported in warfarin-treated patients initiated on Multaq (dronedarone). Monitor INR after initiating dronedarone in patients taking warfarin. Conflict Code: DD – Drug/Drug Interaction Drugs/Diseases Util A: Dronedarone Util B: Warfarin Util C: References: Facts & Comparisons, 2012 Updates. Clinical Pharmacology, 2012 Elsevier/Gold Standard. Multaq Prescribing Information, December 2011, Sanofi-Aventis U.S. LLC.	√		
2. Dronedarone / Atrial Fibrillation (Black Box Warning) Alert Message: Multaq (dronedarone) is contraindicated in patients with atrial fibrillation (AF) who will not or cannot be cardioverted into normal sinus rhythm. In patients with permanent AF, dronedarone doubles the risk of death, stroke, and hospitalization for heart failure. Patients treated with dronedarone should undergo monitoring of cardiac rhythm at least once every 3 months. Conflict Code: MC- Drug/Disease Warning (Black Box) Drugs/Diseases Util A: C Dronedarone Util B: Atrial Fibrillation Util C: References: Multaq Prescribing Information, December 2011, Sanofi-Aventis U.S. LLC. FDA Safety Communication: Review Update of Multaq (dronedarone) and Increased Risk of Death and Serious Cardiovascular Adverse Events. [12-19-2011]. Available at: http://www.fda.gov/Drugs/DrugSafety/ucm283933.htm	√		

3. Bydureon / Byetta ___√___ _____ _____

Alert Message: Therapeutic duplication of exenatide-containing products may be occurring. Bydureon and Byetta both contain the same active ingredient, and therefore should not be used together.

Conflict Code: TD – Therapeutic Duplication
Drugs/Diseases

Util A	Util B	Util C
Bydureon	Byetta	

References:
Bydureon Prescribing Information, Jan. 2012, Amylin Pharmaceuticals, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

4. Bydureon / Insulin √

Alert Message: The concurrent use of Bydureon (exenatide extended-release) with insulin has not been studied and is not recommended.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Bydureon	Insulin	

References:
Bydureon Prescribing Information, Jan. 2012, Amylin Pharmaceuticals, Inc.

5. Bydureon / Medullary Thyroid Cancer & MENS √

Alert Message: Bydureon (exenatide extended-release) use is contraindicated in patients with personal or family history of medullary thyroid carcinoma or in patients with multiple endocrine neoplasia syndrome type 2 (MENS2). Exenatide extended-release has been shown to cause thyroid C-cell tumors at clinically relevant exposures in rats, human relevance is unknown.

Conflict Code: MC – Drug (Actual) Disease Warning **(Black Box)**
Drugs/Diseases

Util A	Util B	Util C
Bydureon	Medullary Thyroid Cancer	
	Multiple Endocrine Neoplasia Syndrome	

References:
Bydureon Prescribing Information, Jan. 2012, Amylin Pharmaceuticals, Inc.

6. Exenatide-All / ESRD & Severe Renal Impairment √

Alert Message: Exenatide-containing products (Byetta & Bydureon) should not be used in patients with severe renal impairment or end-stage renal disease and should be used with caution in patients with renal transplantation. There have been post-marketing reports of altered renal function, sometimes requiring hemodialysis or kidney transplantation.

Conflict Code: MC – Drug (Actual) Disease Warning
Drugs/Diseases

Util A	Util B	Util C
Exenatide-All	ESRD	
	Severe renal Impairment	
	Kidney Transplantation	

References:
Bydureon Prescribing Information, Jan. 2012, Amylin Pharmaceuticals, Inc.
Byetta Prescribing Information, Dec. 2011, Amylin Pharmaceuticals, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

7. Exenatide-All / Warfarin √

Alert Message: The coadministration of an exenatide-containing agent (Byetta & Bydureon) and warfarin may result in increased INR and the possible risk of bleeding. If these agents are used concurrently monitor the patient closely for INR changes during exenatide initiation and dose increases.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Exenatide-All	Warfarin	

References:
Bydureon Prescribing Information, Jan. 2012, Amylin Pharmaceuticals, Inc.
Byetta Prescribing Information, Dec. 2011, Amylin Pharmaceuticals, Inc.

8. Exenatide-All / Type 1 Diabetes & Ketoacidosis √

Alert Message: Exenatide-containing agents (Byetta & Bydureon) are not a substitute for insulin. Exenatide should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

Conflict Code: MC – Drug (Actual) Disease Warning
Drugs/Diseases

Util A	Util B	Util C
Exenatide-All	Type 1 Diabetes Ketoacidosis	

References:
Bydureon Prescribing Information, Jan. 2012, Amylin Pharmaceuticals, Inc.
Byetta Prescribing Information, Dec. 2011, Amylin Pharmaceuticals, Inc.
.

9. Exenatide-All / Antibiotics & Oral Contraceptives √

Alert Message: Exenatide slows gastric emptying. Medications requiring rapid gastrointestinal absorption (e.g., oral contraceptives and antibiotics) should be administered at least one hour prior to exenatide use.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Exenatide-All	Oral Contraceptives Antibiotics	

References:
Bydureon Prescribing Information, Jan. 2012, Amylin Pharmaceuticals, Inc.
Byetta Prescribing Information, Dec. 2011, Amylin Pharmaceuticals, Inc.

*AL Medicaid already has exenatide/pancreatitis warning approved and turned on.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

10. Linezolid / Duration > 28 days √

Alert Message: The safety and efficacy of Zyvox (linezolid) given for longer than 28 days have not been evaluated in controlled clinical trials. Significant adverse events (e.g., myelosuppression, peripheral and optic neuropathy and lactic acidosis) have been reported with the use of linezolid for longer than the maximum recommended duration of 28 days. These events have also been reported in patients receiving shorter courses of therapy.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Linezolid		

Duration: 29 days or more in most current 90 days

References:
Facts & Comparisons, 2012 Updates.
Zyvox Prescribing Information, June 2010, Pfizer Labs.
Narita M, Tsuji BT and Yu VL. Linezolid-Associated Peripheral and Optic Neuropathy, Lactic Acidosis, and Serotonin Syndrome. Pharmacotherapy. 2007 Aug;27(8):1189-1197.

11. Intermezzo / Overutilization Females 18-64 yoa √

Alert Message: The maximum recommended daily dose of Intermezzo (sublingual zolpidem) for women is 1.75 mg. In clinical studies female subjects exhibited decreased clearance of the same dose of sublingual zolpidem as compared to male subjects, leading to a lower dose recommendation for females. The maximum daily dose for men is 3.5mg.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negating)
Intermezzo		Hepatic Impairment

Max Dose: 1.75mg/day
Gender: Female
Age Rage: 18-64 yoa

References:
Intermezzo Prescribing Information, Nov. 2011, Purdue Pharma.

12. Intermezzo / Overutilization Males 18-64 yoa √

Alert Message: The maximum recommended daily dose of Intermezzo (sublingual zolpidem) for men is 3.5 mg. In clinical studies female subjects exhibited decreased clearance of the same dose of sublingual zolpidem as compared to male subjects, leading to a lower dose recommendation for females. The maximum daily dose for females is 1.75 mg.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negating)
Intermezzo		Hepatic Impairment

Max Dose: 3.5 mg/day
Gender: Male
Age Rage: 18-64 yoa

References:
Intermezzo Prescribing Information, Nov. 2011, Purdue Pharma.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

13. Intermezzo / Overutilization 65 yoa and older √

Alert Message: The maximum recommended daily dose of Intermezzo (sublingual zolpidem) for geriatric patients is 1.75 mg. A pharmacokinetic study of 1.75 and 3.5 mg doses of sublingual zolpidem showed that the plasma Cmax and AUC in elderly subjects following the 3.5 mg dose was higher by 34% and 30%, respectively, than the non-elderly subjects.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negating)
Intermezzo		Hepatic Impairment

Max Dose: 1.75mg/day
Age Range: ≥65 yoa

References:
Intermezzo Prescribing Information, Nov. 2011, Purdue Pharma.

14. Intermezzo / Overutilization Hepatic Impairment √

Alert Message: The maximum recommended daily dose of Intermezzo (sublingual zolpidem) for patients with hepatic impairment is 1.75 mg. In a pharmacokinetic study patients with chronic hepatic insufficiency or cirrhosis taking oral zolpidem exhibited increased pharmacokinetic parameters as compared to subjects with normal hepatic function.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)
Intermezzo		Hepatic Impairment

References:
Intermezzo Prescribing Information, Nov. 2011, Purdue Pharma.

15. Intermezzo / CNS Depressants √

Alert Message: The maximum recommended daily dose of Intermezzo (sublingual zolpidem) when taken concurrently with a CNS depressant is 1.75 mg. Concomitant use of these agents may result in additive CNS depression.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)
Intermezzo		Narcotics
		Benzodiazepines
		Barbiturates
		Sedative/Hypnotics
		Muscle Relaxants
		Antipsychotics
		Antihistamines

References:
Intermezzo Prescribing Information, Nov. 2011, Purdue Pharma.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*
16. Indacaterol / Xanthine Derivatives and Steroids	_____	√	_____

Alert Message: Caution should be exercised when Arcapta (indacaterol) is prescribed concurrently with xanthine derivatives or steroids because concomitant administration may potentiate the hypokalemic effect of indacaterol.

Conflict Code: DD- Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Indacaterol	Theophylline	Prednisolone
	Aminophylline	Prednisone
	Dyphylline	Betamethasone
	Budesonide	Cortisone
	Dexamethasone	
	Hydrocortisone	
	Methylprednisolone	

References:
Arcapta Prescribing Information, July 2011, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2011 Gold Standard.
Facts & Comparisons, 2011 Updates.

Stephanie McGee Azar, Acting Commissioner (✓) Approve ( ) Deny 6-27-12 Date

Robert Moon, M.D., Deputy Commissioner and Medical Director (✓) Approve ( ) Deny 6-27-12 Date

Kathy Hall, Deputy Commissioner (✓) Approve ( ) Deny 6/26/12 Date